

06 JUL 2001

091807168

Translation of WO 00/21450 (PCT/EP99/07540)

Device for Carrying Out Medical Interventions and a Method for
Generating an Image

The invention relates to a device for carrying out medical interventions (operations) on the human or animal body, comprising a device for storing first image data of the area to be operated on which are, for example, obtained by means of computer tomography and/or magnetic resonance imaging, and comprising a device for displaying image data.

In contrast to operations in the orthopedic field, the area to be operated on, for example, in brain surgery and liver surgery, will change during the intervention. In the case of, for example, coagulation of a brain tumor there are actually two effects.

The brain tumor, on the one hand, will drop, and, on the other hand, will decrease its volume, wherein the brain will fill out immediately the volume that has been freed by the coagulating tumor. Accordingly, it is required to intraoperatively update pre-operatively obtained image data in order to prevent that, as a result of false or missing information in regard to the actual position of the tumor to be coagulated, damage will be caused to the adjoining brain.

In order to obtain detailed information in regard to the area to be operated on, image-providing methods are used which are, for example, magnetic resonance imaging and computer tomography. Both image-generating methods are suitable only to a limited extent, or

not at all, for intraoperative image generation. Image-generating methods by means of ultrasound can be used intraoperatively, but the image data obtained therewith are usually not detailed enough.

It is therefore an object of the invention to provide a device of the aforementioned kind with which, intraoperatively, sufficiently detailed image data can be obtained and displayed.

According to the invention the above object is solved for a device of the aforementioned kind by an image-generating device, which, for example, operates with ultrasound, for obtaining second image data of the area to be operated on during the operation and an updating device which is configured to compare second image data, obtained at a first point in time, with second image data, obtained at a second point in time that is after the first point in time, and to update the first image data according to the change resulting from the comparison, and to supply the updated first image data to the display device.

In other words, image data, which cannot be obtained or obtained only with difficulty intraoperatively, are however obtained preoperatively with sufficient detail and can be updated and displayed intraoperatively by means of image data which can be obtained more easily but with less detail during operation so that an updated and sufficiently detailed, even though artificially generated, image is obtained and displayed. Accordingly, according to the invention the image data obtained intraoperatively are not themselves displayed but are only used to update substantially more detailed image data obtained preoperatively.

Methods for updating image data are generally known in medical technology, for example, from the following publications:

"Individualizing Anatomical Atlases of the Head" in "Visualization in Biomedical Computing", 1996; "Medical Image Segmentation Using Topologically Adaptable Surfaces", in "CVRMed-MRCAS '97", March 1997, pp. 23-32; "Segmentation Using Deformable Models with Affinity-Based Localization", in "CVRMed-MRCAS '97", March 1997, pp. 54-62; "Volumetric Medical Images Segmentation Using Shape Constrained Deformable Models", in "CVRMed-MRCAS '97", March 1997, pp. 13-22; "Shape-Based Segmentation and Tracking in 4D Cardiac MR Images", in "CVRMed-MRCAS '97", March 1997, pp. 43-52; "Decimation of Iso-Surfaces with Deformable Models", in "CVRMed-MRCAS '97", March 1997, pp. 84-92.

According to the invention it can be preferably provided that the updating device updates the first image data in certain time intervals. The time intervals are adjusted in this context to the specific requirements of the operation to be performed. Some changes, such as, for example, shrinkage in connection with coagulation, require that updating is performed essentially in real time. This can mean many updates per second.

However, it may also be provided that the updating device updates the first image data every time when the changes resulting from the comparison surpass a certain limit. In other words, an update is carried out only when this is required because changes that have to be considered have occurred. In this way, the computing time and computing capacity required for the update can be reduced to a minimum.

Preferably, the device according to the invention has a surgical robot which is configured to carry out, taking into account the updated first image data, manually input commands and/or to automatically perform at least one operation step according to a

predetermined program. In other words, the surgical robot works automatically based on the respectively updated first image data and/or it is guided by a surgeon who can take the respectively updated image data from the display device and who has optionally direct visual contact with the area to be operated on by means of endoscopic devices.

According to the invention it can be provided that the surgical robot is configured to work within the limits of a predetermined volume within the area to be operated on and represented by the updated first image data. This volume can be, for example, a brain tumor to be coagulated. Accordingly, the surgical robot in this case is limited to the coagulation of the tumor so that the adjoining brain substance is not endangered.

According to the invention, the surgical robot be configured to maintain a predetermined spacing to a predetermined boundary surface in the area to be operated on and represented by the updated first image data. In this connection it holds true also that the brain substance bordering the area to be operated on is protected against damage by the surgical robot.

Moreover, according to the invention, the surgical robot can be configured to move to a predetermined point in the area to be operated on and represented by the updated first image data. Such a target point can be, for example, the center of a brain tumor to be coagulated.

According to the invention, it is preferred to provide a device for inputting the limit volume, the boundary surface and/or the target point. By doing so, the surgeon has the possibility to set preoperatively and/or intraoperatively the limits for the surgical

robot required for safety and described above or to define a target point which is to be reached by the surgical robot at the beginning, during the course, or at the end of the operation.

According to the invention, it is preferred to provide a calibrating device which is to be arranged fixedly on the body and which has at least one landmark which, relative to the body, represents a fixed common reference point for the first and the second image data. Such a calibrating device serves, for example, for enabling adjusting, directly before the beginning of the operation, image data, obtained by ultrasound, with image data obtained preoperatively by way of computer tomography or by magnetic resonance imaging by means of so-called co-registration.

The calibrating device, according to the invention, is preferably formed by a stereotactic frame. Of course, other (equivalent) devices can be used for this purpose.

The invention concerns moreover a method for generating an image of the human or animal body.

As has been mentioned above, there are situations, for example, during an operation, in which only such image generating methods can be used which provide insufficiently detailed image data.

The invention also concerns the object to provide a method of the aforementioned kind which provides intraoperatively detailed image data even when a correspondingly detailed image generating method cannot be used intraoperatively.

According to the invention, the above object is solved by a method with the following steps:

- storing first image data of the body obtained, for example, by means of computer tomography or magnetic resonance imaging,
- recording second image data of the body, for example, by means of ultrasound, at a first point in time and a second point in time which is after the first point in time;
- comparing with one another the second image data recorded at the first and the second points in time;
- updating the first image data according to the change resulting from the comparison; and
- displaying the updated first image data.

As has been mentioned above in detail with reference to the device according to the invention, according to the method of the invention in certain situations, i.e., for example, during an operation, an image generating method is used which provides less detailed image data, wherein it is not these less detailed image data but the detailed image data updated based on the change of the less detailed image data that are displayed.

It is expressly stated that the method according to the invention relates exclusively to the generation or display of an image of the human or animal body and not to a diagnostic method or therapy. For a diagnostic method it is indeed required not only to generate and display the image but also to evaluate it. For a therapy, measures on the body are required which surpass the pure generation and the pure display.

According to the invention, the first point in time and the position of the body are selected upon recording of the second image data such that the second image data taken at the first point in time correspond to the stored first image data.

In other words, a calibration is performed inasmuch as the first and the second image data are adjusted once relative to one another in that they represent one and the same state of the body.

According to the invention, the step of updating can be performed in predetermined time intervals.

However, it can also be provided that the step of updating is performed (only) when the changes resulting from the comparison surpass a predetermined limit. This makes it possible to save computing time and computing capacity.

In the following, the invention is explained in more detail with the aid of preferred embodiments with further details with reference to the attached drawing, wherein the drawing

shows schematically an embodiment of the device according to the invention.

The core piece of the device according to the invention is a computer 10 with a comparator 12. By means of a stereotactic frame 14 fixedly connected on the body, for example, connected to the head for neurosurgical purposes, a computer tomogram and/or a magnetic resonance image is recorded preoperatively, with consideration of landmarks, by means of a computer tomographic or a magnetic resonance imaging device 16. The obtained image data are then stored in a memory 18. At the beginning of the operation,

by using the same stereotactic frame 14, an ultrasound image is recorded by means of an ultrasound device 20 which is then adjusted for calibration purposes by means of the computer tomogram or the magnetic resonance image.

The preoperatively obtained computer tomogram or magnetic resonance image is displayed by means of the display, for example, in the form of a monitor 22.

During the course of the operation, which is performed, for example, by means of a surgical robot 24, ultrasound images are produced again and again which are compared with the preceding ultrasound images. The deviations which are obtained thereby serve for changing the computer tomogram or the magnetic image accordingly. The most recent version of the computer tomogram or the magnetic resonance image which has been updated accordingly is supplied, on the one hand, from the computer 12 to the monitor 22 so that the surgeon is informed continuously about the course of the operation. On the other hand, it is also used in order to control the surgical robot 24, wherein this includes, for example, that it is being input with a volume to be operated (changing during the course of the operation), wherein it is furthermore also programmed to maintain a predetermined spacing from a boundary surface previously input into the computer.

The surgical robot 24, *inter alia*, is capable of the following:

- automatic limitation to a space defined by the surgeon;
- automatically maintaining a predetermined spacing to a surface in the area operated and/or,

- return to a preselected point in the area to be operated on or along the operative access path.

Programming of this robotic performance is realized in that the surgeon provides manually limit values on slice images of pre-operatively obtained image data sets which then result in points, distances or spaces and can be used for the control of the surgical robot 24. Such a point can be a starting or target point or a return point on an operative access path. A distance can be a connecting line between different points on an access path to an area to be operated on or within the area to be operated on. A space or volume can be the periphery of a solid or cystic tumor or a cyst or its wall whose outer boundary is not to be touched by a surgical instrument.

For controlling the spatial conditions and their changes during an operation, the surgeon uses the intraoperative ultrasound imaging.

Before the operation, a 3-D data set is generated with an image-forming method such as magnetic resonance imaging or computer tomography. This data set serves as a reference image for the further steps. During this examination, the stereotactic frame 14 is fastened on the head of the patient for neurosurgical purposes. This frame 14 contains landmarks which can be used for calibration or co-registration of the systems at the beginning of the operation. At the point of beginning the operation, the surgical robot 24, which is, for example, in the form of a robot arm, is brought into a fixed predetermined spatial relation to the mounted stereotactic frame 14 and is fixedly mounted. Subsequently, the landmark points are traced with the tip of the operating instrument functioning as the calibration device so that an unequivocal relation between the working space of the robot and the space of

the preoperatively produced images is generated. A similar fixed correlation is then generated between the stereotactic frame 14 and the ultrasound head 20 to be implanted for generating three-dimensional ultrasound images. With this fixed predetermined correlation between the preoperative image space and the intraoperative ultrasound image space there is the possibility to initially simply determine changes in the area to be operated on by means of ultrasound imaging.

Subsequently, a so-called co-registration between the preoperative and the intraoperative images is carried out with the goal to transfer this information in real time to the robot arm and to thus adjust the planned operation steps to the momentary spatial conditions. Moreover, this co-registration step makes it possible to maintain a respective qualitatively highest display of the momentary conditions with regard to the image representation, which serves as an orientation for the surgeon during the intervention, in that by means of the co-registration, for example, the preoperative 3-D magnetic resonance data set is adjusted and displayed according to the spatial changes recognized intraoperatively by the ultrasound image. The co-registered changed magnetic resonance data set as an artificial product of a co-registration step will thus produce images which have an appearance as if, intraoperatively, magnetic resonance imaging had been performed. In reality, however, the image information of the intraoperative ultrasound imaging has been used to alter the preoperative magnetic resonance data set such that the new magnetic resonance image corresponds to the actual spatial conditions and is identical to the actual ultrasound image. In this way, image details of the magnetic resonance image, which cannot be shown in the ultrasound image, can optionally also be shown in this modified form that is adjusted to the momentary situation so that the

surgeon is presented with a high resolution virtual image of the area to be operated on. On the other hand, it is also possible to represent image contents which do not occur in the pre-operative image, i.e., which are obtainable only by means of ultrasound.

In detail, this co-registration mechanism means that the pre-planned target points, distances, surfaces, and spaces of the robot space are adjusted respectively to the momentary conditions within the area to be operated on. They make possible an updated precise operation.

This means that, for example, when a coagulation probe is activated in order to coagulate the central area of a tumor, the entire tumor will shrink as a result of the coagulation process and the tumor boundaries preset pre-operatively by the surgeon no longer correspond to the actual tumor boundaries. The device according to the invention is able to observe and to document the movements of these preset boundaries, i.e., to register the volume changes and to transmit these to the surgical robot. The volume which has been predetermined during preoperative planning by the surgeon is referred to as the "alarm volume". The control software for registration of changes of this volume or changes of the surface of this volume is referred to as the "alarm volume adaptation tool" (AVAT) .

One of the programs for surgical robot performance is designed to coagulate automatically a volume pre-planned by the surgeon. In this context, the automatic coagulation process is stopped as soon as the momentarily coagulated volume has reached at one location the planned volume. In this connection, the performance of the AVAT must be taken into account which ensures that the planned volume toward the end of the coagulation process no longer

corresponds to the momentary volume because the entire tumor during the coagulation process has shrunk. The coagulation process is thus adapted according to the movement of the tumor surface during the coagulation process and terminated earlier.

The next operation step is then comprised of, for example, moving the tip of the coagulation probe into the center of that new sphere which contains the greatest possible residual tumor proportion to be coagulated next. In this connection, the AVAT must be taken into account again between planned and momentary volume. Moreover, for this and the subsequent steps for the third, fourth etc. coagulation, the movement of the probe tip is guided from the momentary position to a predetermined entry point and from there along an access path to the new target point.

A further program course is, for example, provided in order to scan the inner surface of a cystic tumor with a surgical instrument, to first coagulate a predetermined layer thickness and to then scrape off the coagulated tissue. In this context, the distance maintenance program is activated which ensures that a safety distance is maintained relative to the coagulation boundary so that bleeding is prevented during the tumor removal.

The features of the invention disclosed in the above description, the claims as well as the drawing can be important individually as well as in any chosen combination for the realization of the invention in its different embodiments.